UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

KAYLA DOHERTY, an Individual residing in the Town of Pittsfield, County of Somerset, and State of Maine,	)	
Plaintiff,	)	
v.	)	
	)	Case No._____
MERCK & CO., INC.,	)	
and	)	
UNITED STATES OF AMERICA,	)	
Defendants	)	

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff Kayla Doherty, by and through the undersigned counsel, hereby complains against Defendants as follows:

INTRODUCTION

1. This is an action for personal injuries sustained by Plaintiff KAYLA DOHERTY as a result of the negligent failure to properly insert in her arm the contraceptive prescription drug Implanon and/or Nexplanon.

2. Implanon and/or Nexplanon is a defective implantable birth control device researched, developed, manufactured, marketed, promoted, advertised, and sold by Defendant MERCK & CO., INC. Nexplanon as well as its predecessor drug Implanon both have a history of failed attempts to insert the device due to a defectively designed applicator, which has in many cases including this one resulted in unplanned pregnancy.

3. This action arises in part under the Federal Tort Claims Act ("FTCA") because the doctor who negligently failed to properly insert the Implanon and/or Nexplanon device in Plaintiff KAYLA DOHERTY'S arm was deemed an employee of the UNITED STATES working at a HealthReach Community Health Center.

THE PARTIES

4. Plaintiff KAYLA DOHERTY is an individual residing in the Town of Pittsfield, County of Somerset, and State of Maine.

5. Defendant MERCK & CO., INC. (hereinafter "MERCK") is a New Jersey corporation organized, existing, and conducting business in the State of New Jersey with a principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey.

6. Several business entities organized and existing under the laws of the State of New Jersey using the name ORGANON have been acquired by and currently operate as subsidiaries of MERCK, including the following entities: ORGANON USA, INC., ORGANON BIOSCIENCES NV, ORGANON PHARMACEUTICALS USA, INC., ORGANON INTERNATIONAL, INC., and NV ORGANON (hereinafter collectively referred to as "ORGANON").

7. In a 2008 transaction, a Delaware entity named SCHERING-PLOUGH CORPORATION acquired ORGANON and either expressly or impliedly assumed the liabilities and obligations of ORGANON, including liability for its manufacturing, design, licensing, packaging, distributing, selling, marketing, and/or introducing into interstate commerce the predecessor to Nexplanon, a defective contraceptive device called Implanon.

8. In or about November of 2009, MERCK acquired and/or merged with SCHERING-PLOUGH CORPORATION and either expressly or impliedly assumed the

liabilities of both SCHERING-PLOUGH CORPORATION and ORGANON as a result of that transaction.

9. For reasons set forth more fully below, MERCK discontinued Implanon in or about November of 2010 and replaced the drug with Nexplanon, a nearly identical implantable contraceptive device manufactured and packaged by ORGANON, a division of MERCK.

10. Lovejoy Health Center, a Maine nonprofit corporation with a principal place of business located at 7 School Street, Suite 1, in Albion, Maine, is considered a HealthReach Community Health Center ("the Lovejoy HRCHC") within the meaning of the Federally Supported Health Centers Assistance Act of 1992.

11. Defendant United States of America (hereinafter "UNITED STATES") deemed the Lovejoy HRCHC eligible for FTCA coverage effective January 1, 2011 pursuant to 42 U.S.C. § 233(g), and coverage has continued from that date without interruption.

12. At all times herein relevant, the UNITED STATES has deemed the employees and/or contractors of the Lovejoy HRCHC eligible for FTCA coverage.

13. The physician whose negligence caused KAYLA DOHERTY'S injuries, Amanda Ruxton, DO, is considered a Federal employee and/or contractor of the Lovejoy HRCHC for purposes of the FTCA.

14. Defendant UNITED STATES is liable for the acts and omissions of all agents, contractors, and employees of the Lovejoy HRCHC under the FTCA.

JURISDICTION AND VENUE

15. Plaintiff KAYLA DOHERTY filed an administrative tort claim pursuant to the FTCA within two years of the accrual of this cause of action, on or about February 18, 2014, by delivering a completed form SF95 to the appropriate Federal agency for consideration, the

United States Department of Health and Human Services ("DHHS"), stating a demand of $250,000.00 for the claim.

16. DHHS acknowledged receipt of Plaintiff's claims on or about February 19, 2014.

17. KAYLA DOHERTY has exhausted her administrative remedies within the meaning of the FTCA because more than six months have elapsed since Plaintiff filed her claim, and the UNITED STATES has failed to respond, which constitutes a denial of the claim under 28 U.S.C. § 2675.

18. The Court has original Federal subject matter jurisdiction in this case pursuant to 28 U.S.C. § 1346(b).

19. For purposes of Plaintiff's claim against Defendant MERCK, diversity jurisdiction exists pursuant to 28 U.S.C. § 1332 because Plaintiff and Defendant MERCK are not citizens of the same state and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

20. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) because the United States is a Defendant and the Plaintiff resides in this district. Further, a substantial part of the events or omissions alleged herein occurred in this judicial district.

FACTS

21. Defendant MERCK and/or its subsidiary ORGANON began researching, developing, testing, and marketing an implantable birth control device called Implanon more than 15 years ago.

22. Implanon is a 4 cm long and 2 cm wide single rod with an ethylene vinylacetate copolymer core containing 68 mg of etonogestrel, a type of hormone (progestin) effective at inhibiting ovulation and therefore preventing pregnancy.

23. Implanon is inserted just under the skin on the inner side of a woman's arm between the bicep and tricep muscles, using a syringe-like applicator called a trocar; the device is intended to remain in place for a period of three years while maintaining ovulation suppression.

24. MERCK and/or its subsidiaries first introduced Implanon to the Indonesian market in 1998.

25. Implanon was introduced in the Australian market in 2001. In the 18 months that followed, an unprecedented number of adverse events were reported, including nearly 100 unintended pregnancies.

26. Risk management companies in Australia responded to these adverse events by restricting the availability of Implanon and establishing guidelines, checklists, and consent forms for practitioners and patients alike to be made aware of the risks associated with failed insertion.

27. Failed Implanon insertion resulted because the rod to be inserted in a woman's arm got stuck in the applicator. Practitioners erroneously believed that insertion had been successful and failed to detect that the rod remained stuck in the applicator after the procedure.

28. At all times herein relevant, MERCK and/or its subsidiaries were responsible for, or involved in, designing, manufacturing, marketing, developing, testing, labeling, promoting, distributing and/or selling Implanon.

29. By 2006, the dangers of Implanon were well known to MERCK through its continued and long-term testing, developing, manufacturing, distributing, licensing, labeling, and marketing of the product outside the United States.

30. In July 2006, the United States Food and Drug Administration ("FDA") approved the use of Implanon as a hormone-releasing birth control implant to prevent pregnancy.

31. However, in obtaining this approval, MERCK failed to accurately inform the

FDA of all adverse events associated with Implanon.

32. MERCK knew or should have known that Implanon was not as effective as was claimed because of the design flaw described above.

33. Alternatively, MERCK knew or should have known that Implanon involved an unreasonably high risk of failed insertion that could lead to unplanned pregnancy.

34. As a result of the problems associated with Implanon, MERCK discontinued the drug in or about 2010 and began testing, developing, manufacturing, distributing, licensing, labeling, and marketing a new drug called Nexplanon.

35. Nexplanon was nearly identical to Implanon except that the Nexplanon rod contained 15 mg of barium sulphate to make it radiopaque, meaning it would show up on x-ray if the rod migrated after insertion, which was another known risk of the device.

36. In addition, MERCK attempted to redesign the applicator sold as part of Nexplanon, because of the known problems associated with: (1) identifying proper insertion, and (2) ensuring that the rod had not fallen out of the applicator before insertion.

37. Neither of these steps taken by MERCK to improve upon the Nexplanon applicator was sufficient to reduce the known, substantial risk of failed insertion.

38. Nexplanon received FDA approval and was available in the United States in or around November 2011.

39. In receiving FDA approval of Nexplanon, MERCK again misled the FDA about the known risks of failed insertion associated with the device.

40. MERCK knew or should have known that practitioners had significant difficulties with insertion of both Implanon and Nexplanon.

41. Although insertion of the rod with both the Implanon and Nexplanon applicator

has been challenging for practitioners, MERCK's website contains misleading advertisements, stating for instance that the mean clinical time for insertion of Nexplanon is less than one minute.

42. MERCK has a continuing duty to warn of the significant risk of failed insertion with its second-generation implantable contraception Nexplanon.

43. MERCK failed to do adequate post-marketing studies of the safety and effectiveness of Implanon and Nexplanon's design, warnings, and insertion methods.

44. The risks of failed insertion exceed the alleged benefits of Implanon and/or Nexplanon.

45. On January 26, 2012, Plaintiff KAYLA DOHERTY visited the Lovejoy HRCHC to inquire about birth control options. The doctor she saw, Amanda Ruxton, DO, was deemed a Federal employee of the Lovejoy HRCHC and acting within the scope of her employment when she treated KAYLA DOHERTY.

46. Dr. Ruxton recommended implantable contraception in the form of Implanon or Nexplanon for KAYLA DOHERTY.

47. On February 28, 2012, Plaintiff KAYLA DOHERTY, then age 20, returned to the Lovejoy HRCHC for insertion of the Implanon or Nexplanon device.

48. Although the FDA-approved product labeling and packaging for Implanon and/or Nexplanon describes the importance of receiving informed consent from the patient before insertion of the drug, Dr. Ruxton failed to obtain consent from KAYLA DOHERTY before moving forward with the insertion procedure.

49. Dr. Ruxton used a syringe to create a hole in Plaintiff's arm to insert the Implanon or Nexplanon device.

50. Dr. Ruxton never explained the device, its risks, dangers, or side effects.

51. Dr. Ruxton never examined Plaintiff's arm, or had Plaintiff examine her own arm, to see if the device was properly inserted.

52. Dr. Ruxton never gave Plaintiff any handouts, pamphlets or information regarding Implanon or Nexplanon.

53. Although the standard of care required that Dr. Ruxton create an accurate medical record stating which arm she had used to insert the Implanon or Nexplanon device, no such documentation exists in Plaintiff's medical records.

54. Implanon and/or Nexplanon product literature clearly emphasizes the importance of checking for proper insertion after the procedure is complete, yet Dr. Ruxton failed to do so.

55. Although the product literature and the standard of care both require that patients be informed about the risks associated with failed insertion and checking for proper insertion and positioning of the Implanon and/or Nexplanon device on a regular basis, KAYLA DOHERTY was never provided with this information.

56. Beginning in September 2013, Plaintiff began feeling ill.

57. As her symptoms continued and she missed her menstrual cycle, Plaintiff took multiple pregnancy tests at home, all of which came back positive.

58. Plaintiff was devastated upon learning of her pregnancy because she had made responsible, reasonable efforts to avoid having a baby until she had more economic stability.

59. When KAYLA DOHERTY became pregnant at the age of 21, she was a certified nursing assistant earning $8.70 per hour.

60. KAYLA DOHERTY had hoped to attend nursing school and establish herself in the profession before she started a family.

61. On October 16, 2013, Plaintiff visited the Lovejoy HRCHC where the medical

staff confirmed her positive pregnancy test.

62. Despite extensive effort, the staff at the Lovejoy HRCHC was unable to palpate the Implanon or Nexplanon device in Plaintiff's arm, and they could not discern which arm had been the site of implantation due to Dr. Ruxton's incomplete medical documentation.

63. The staff at Lovejoy's HRCHC told Plaintiff that they would speak with Dr. Ruxton and she would call Plaintiff to discuss into which arm the device had been implanted; Dr. Ruxton never called Plaintiff.

64. Dr. Ruxton's staff cancelled Plaintiff's next appointment and the Lovejoy HRCHC directed her to Inland Hospital for treatment.

65. On October 23, 2013, Plaintiff visited Inland Hospital in Waterville, Maine for removal of her Implanon or Nexplanon device.

66. Plaintiff had ultrasounds of her arms performed where the device should have been implanted; however, the device could not be found.

67. Plaintiff spoke with a nurse from the Lovejoy HRCHC on or about October 24, 2013. The nurse asked Plaintiff how things went at Inland Hospital. When Plaintiff indicated that the device could not be found in her body, the nurse responded, "Dr. Ruxton believes it was never inserted."

68. Upon information and belief, Dr. Ruxton was never properly trained to insert Implanon/Nexplanon devices.

69. Over the next nine months of her pregnancy, KAYLA DOHERTY endured nausea, mental and physical pain and suffering, insomnia, swelling, and weight gain. She was required to attend multiple medical appointments for treatment and monitoring. She also incurred medical and related expenses as a result of her pregnancy. KAYLA DOHERTY

suffered losses and costs including care for hospitalization, physician care, monitoring, treatment, medication and supplies.

70. Plaintiff missed time from her work and therefore suffered lost wages as a result of her unplanned pregnancy.

71. On June 9, 2014, after a long and painful delivery, KAYLA DOHERTY gave birth to a baby boy named Blake David Mann.

72. Since her child's birth, KAYLA DOHERTY has undergone mental health counseling. Plaintiff has suffered emotional distress related to her pregnancy and the complications associated with rearing a child as a single mother without adequate preparation, planning, and economic resources.

COUNT I
(UNITED STATES)
MEDICAL NEGIGENCE

73. Plaintiff repeats the allegations contained in Paragraphs 1 through 72 of her Complaint as if fully set forth herein.

74. Defendant UNITED STATES, by and through its Federally deemed agents and/or employees, breached the applicable standard of care when treating Plaintiff KAYLA DOHERTY.

75. Amanda Ruxton, DO selected and pursued a course of treatment with which she was unfamiliar and not properly trained when she recommended Implanon or Nexplanon to KAYLA DOHERTY; in so doing, Dr. Ruxton failed to exercise the level of ordinary skill, care, and judgment possessed by members of her profession in like situations.

76. In breaching the applicable standard of care, Defendant UNITED STATES proximately caused KAYLA DOHERTY to suffer harm and personal injuries.

WHEREFORE, Plaintiff requests that this honorable Court enter judgment in her favor on Count I and order the UNITED STATES to pay damages consistent with the evidence in this case together with interest, costs, reasonable attorneys' fees, and order other further relief as the Court deems just and appropriate.

COUNT II
(UNITED STATES)
INFORMED CONSENT

77. Plaintiff repeats the allegations contained in Paragraphs 1 through 76 of her Complaint as if fully set forth herein.

78. Amanda Ruxton, DO, as an agent and/or employee of Defendant UNITED STATES working within the scope of her employment, had a duty to obtain Plaintiff's informed consent to treatment by disclosing to her accurate and appropriate information about Implanon or Nexplanon, including without limitation the drug's risks and benefits.

79. In obtaining KAYLA DOHERTY'S informed consent, Defendant furthermore had a duty to disclose reasonable alternatives to the use of Implanon and/or Nexplanon, given the historical risk of failed insertion associated with this drug.

80. Defendant failed to provide KAYLA DOHERTY with important product information explaining the risks and benefits of Implanon or Nexplanon.

81. Defendant UNITED STATES, by and through its agent Amanda Ruxton, DO, breached the above duty to provide informed consent to KAYLA DOHERTY.

82. Defendant's failure to obtain informed consent from KAYLA DOHERTY breached the standard of practice among members of the same health care profession with similar training and experience situated in the same or similar communities.

83. If Defendant had provided accurate information to KAYLA DOHERTY

regarding the risks of failed insertion related to this product, KAYLA DOHERTY would not have provided her consent to this course of treatment.

84. A reasonable person operating under the same circumstances as KAYLA DOHERTY on February 28, 2012, with the same information about the risk of failed insertion associated with Implanon or Nexplanon, would not have consented to this method of birth control.

WHEREFORE, Plaintiff requests that the Court enter judgment in her favor and against the UNITED STATES, and award damages for personal injuries sustained by the Plaintiff, as well as interest, costs, attorney's fees, and such other and further relief as this Court deems just and appropriate.

COUNT III
(MERCK)
STRICT PRODUCTS LIABILITY
14 M.R.S. § 221

85. Plaintiff repeats the allegations contained in Paragraphs 1 through 84 of her Complaint as if fully set forth herein.

86. MERCK sold Implanon or Nexplanon to Plaintiff in a defective condition unreasonably dangerous to KAYLA DOHERTY.

87. The Implanon or Nexplanon device and applicator reached Plaintiff without significant change in the condition in which it was sold.

88. The device was used in a reasonably foreseeable manner by Plaintiff.

89. The aforementioned product defects proximately caused Plaintiff to suffer multiple personal injuries and harm.

WHEREFORE, Plaintiff requests that this honorable Court enter judgment in her favor on Count III and order MERCK to pay damages consistent with the evidence in this case

together with interest, costs, reasonable attorneys' fees, and order other further relief as the Court deems just and appropriate.

COUNT IV
(MERCK)
BREACH OF IMPLIED WARRANTY
11 M.R.S. §§ 2-314; 2-715

90. Plaintiff repeats the allegations contained in Paragraphs 1 through 89 of her Complaint as if fully set forth herein.

91. MERCK is a merchant with respect to the kind of contraceptive birth control goods sold to Plaintiff.

92. Based on the product defects described above, the Implanon or Nexplanon device and applicator used on KAYLA DOHERTY on February 28, 2012 was not merchantable because it was not:

a. Able to pass without objection in the trade;

b. Of fair average quality;

c. Fit for the ordinary purpose for which such goods are used;

d. Adequately contained, packaged, or labeled; and

e. Conforming to the promises or affirmations of fact made on the container or label.

93. Defendant's breach of implied warranty caused Plaintiff to suffer harm and personal injuries.

WHEREFORE, Plaintiff requests that this honorable Court enter judgment in her favor on Count IV and order MERCK to pay damages consistent with the evidence in this case together with interest, costs, reasonable attorney's fees, and order other further relief as the Court deems just and appropriate.

COUNT V
(MERCK)
BREACH OF EXPRESS WARRANTY
11 M.R.S. §§ 2-313; 2-715

94. Plaintiff repeats the allegations contained in Paragraphs 1 through 93 of her Complaint as if fully set forth herein.

95. MERCK made statements and representations about the effectiveness of Implanon and Nexplanon, including without limitation that the device was "more than 99% effective" and that mean insertion time was "less than one second."

96. The product did not possess the quality and fitness to the extent warranted by MERCK.

97. The ability of Implanon and/or Nexplanon to be properly inserted in a woman's arm and prevent pregnancy formed the basis of the bargain by which MERCK sold the product to Plaintiff.

98. MERCK's breach of express warranty caused Plaintiff to suffer harm and personal injuries.

WHEREFORE, Plaintiff requests that this honorable Court enter judgment in her favor on Count V and order MERCK to pay damages consistent with the evidence in this case together with interest, costs, reasonable attorneys' fees, and order other further relief as the Court deems just and appropriate.

COUNT VI
(MERCK)
Negligence

99. Plaintiff repeats the allegations contained in Paragraphs 1 through 98 of her Complaint as if fully set forth herein.

100. MERCK owed Plaintiff a duty of care to act as a reasonable drug manufacturer

when designing, manufacturing, marketing, advertising, distributing and selling Implanon and/or Nexplanon.

101. MERCK failed to exercise due care under the circumstances and therefore breached this duty of care by:

a. Failing to properly and thoroughly test Implanon and Nexplanon before releasing the drug(s) to the market;
b. Failing to properly and thoroughly analyze the data resulting from the pre-market tests of Implanon and Nexplanon;
c. Failing to conduct sufficient post-market testing and surveillance of Implanon and Nexplanon;
d. Designing, manufacturing, marketing, advertising, distributing, and selling Implanon to consumers, including Plaintiff, who was without adequate warning of the significant and dangerous risks of Implanon and Nexplanon, and without proper instructions to avoid the harm which could foreseeably occur as a result of using the drug;
e. Failing to exercise due care when advertising and promoting Implanon and Nexplanon; and
f. Negligently continuing to manufacture, market, advertise, and distribute Implanon and Nexplanon after Defendant knew or should have known of its adverse effects.

102. As a direct and proximate consequence of MERCK's actions, omissions, and misrepresentations, KAYLA DOHERTY suffered harm and personal injuries.

WHEREFORE, Plaintiff requests that this honorable Court enter judgment in her favor on Count VI and order MERCK to pay damages consistent with the evidence in this case together with interest, costs, reasonable attorneys' fees, and order other further relief as the Court deems just and appropriate.

COUNT VII
(MERCK)
NEGLIGENT MISREPRESENTATION

103. Plaintiff repeats the allegations contained in Paragraphs 1 through 102 of her Complaint as if fully set forth herein.

104. In the ordinary course of its business, MERCK made false statements of material

fact to Plaintiff and her physician regarding the effectiveness of Implanon and Nexplanon and its ability to be properly inserted and remain in place to prevent pregnancy.

105. Plaintiff's decision to use Implanon and Nexplanon was based on MERCK's negligent misrepresentations about the product's effectiveness.

106. MERCK failed to exercise reasonable care and competence in obtaining and communicating the above information to Plaintiff.

107. MERCK knew or should have known that the above representations were false and not completely accurate at the time the representations were made and relied on by Plaintiff.

108. KAYLA DOHERTY justifiably relied on the above representations as true and acted upon them, causing her to suffer harm and personal injuries.

WHEREFORE, Plaintiff requests that this honorable Court enter judgment in her favor on Count VII and order MERCK to pay damages consistent with the evidence in this case together with interest, costs, reasonable attorneys' fees, and order other further relief as the Court deems just and appropriate.

JURY TRIAL DEMAND

Plaintiff KAYLA DOHERTY hereby demands a jury trial on all matters so triable under the laws and Constitution of the United States and the State of Maine.

Dated: March 24, 2015

/s/ Laura H. White

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